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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,637	03/24/2004	Jun Feng	DPP-IV-5004-C2	8940
32793	7590	03/19/2008		
TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			EXAMINER	
			HABTE, KAHISAY	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/809,637

Applicant(s)

FENG ET AL.

Examiner

Kahsay T. Habte

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 27-29 and 31 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 13, 27-29 and 31 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date 10/17/07 & 2/20/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. Claims 13, 27-29 and 31 are pending in this application.

Response to Amendment

2. Applicant's amendment filed 02/20/2008 in response to the previous Office Action (08/20/2007) is acknowledged. Rejection of claims 13, 27-29 and 31 under 35 U.S.C. § 112, second paragraph (items 13b-13c) and the prior art rejections (8-12) have been obviated. The obviousness-type double patenting rejection (items 5-7) has been maintained. The second paragraph rejection (item 13a) has been maintained. Applicant's amendment also raises new issue that needs further rejection.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement, filed on 02/20/2008 and 10/17/2007 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Note that the two NPL references (Hcaplus 121:35089 and Hcaplus 122:132810) cited in IDS (02/20/2008) have not been considered, because they don't have a valid date. Said references are search results from Hcaplus and abstracts of Tetrahedron Letters and Journal of Organic Chemistry. It is recommended that applicants submit the specific publications of said search result e.g. Hcaplus 121:35089 "An abstract of Tetrahedron Letters (1994), 35(4), 531-4".

The same problem appears in IDS (10/17/2007).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 13, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-15, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 13, 27-29 and 31 and claims 1, 3-15, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments

Applicant's argument filed 02/20/2008 has been fully considered but it is not persuasive.

Applicants intend to address the rejection when one or both of the applications are otherwise in condition for allowance.

6. Claims 13, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 of copending Application No. 10/809,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 13, 27-29 and 31 and

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claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 of copending Application No. 10/809,635.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments

Applicant's argument filed 02/20/2008 has been fully considered but it is not persuasive.

Applicants intend to address the rejection when one or both of the applications are otherwise in condition for allowance.

7. Claims 13, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-16, 19-20, 28-29, 32-38 and 48 of copending Application No. 10/809,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 13, 27-29 and 31 and claims 1, 7-16, 19-20, 28-29, 32-38 and 48 of copending Application No. 10/809,638.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments

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Applicant's argument filed 02/20/2008 has been fully considered but it is not persuasive.

Applicants intend to address the rejection when one or both of the applications are otherwise in condition for allowance.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 28 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 13, 28 and 31, the phrase "monovalent radicals derived from....., carbonyl groups, sulfonyl groups and sulfinyl groups" is a new matter. There is no support for the broader language monovalent radicals derived from carbonyl groups, sulfonyl groups and sulfonyl groups. According to the specification at page 12, carbonyl is defined as:

[0070] "Carbonyl" means the radical -CO-. It is noted that the carbonyl radical may be further substituted with a variety of substituents to form different carbonyl groups including acids, acid halides, aldehydes, amides, esters, and ketones.

and not as monovalent radical derived from carbonyl. The same is true for the definitions of sulfonyl groups and sulfonyl groups. See also second paragraph rejection.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 27-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 13 or elsewhere in the claims, the phrase "monovalent radicals derived from thiols, carbonyl groups, sulfonyl groups and sulfinyl groups" is not clear. What are covered by a monovalent radicals derived from carbonyl groups, sulfonyl groups and sulfonyl groups and what are not? Note that originally the claims 13 and 31 recite "a carbonyl group, imine group, sulfonyl group and sulfonyl group, and monovalent radicals derived from thiols", but now the claim language is amended to a broader and unclear claim language "monovalent radicals derived from thiols, carbonyl groups, sulfonyl groups and sulfinyl groups". Is the carbonyl substituted at the C or at the oxygen? The same is true for the sulfonyl and sulfinyl groups.

Response to arguments

Applicant's argument filed 02/20/2008 has been fully considered but it is not persuasive.

Applicants argue that "those skilled in the art would readily understand that 'carbonyl' when used as part of Markush group to describe possible substituents, refers to radicals derived from carbonyls. However solely for the purpose of advancing prosecution of the present application, claims 13, 28 and 31 are being amended to recite that the substituents include "monovalent radicals derived from carbonyl groups". The examiner disagrees with applicant's argument. Radicals derived from carbonyls is unclear and broader than that has no support in the specification. It is recommended applicants change the carbonyl group to "oxo" and amend the claims as "an oxo group, sulfonyl groups, sulfonyl groups..." to overcome this rejection.

b. In claims 13 and 31, the phrase "with the proviso that at least one R_8 serves as V" is not clear. What is V? Note that applicants amended claims 13 and 31 and deleted the definition of V. There is definition for UV and not for U and V separately.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9.00- 5:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Kahsay T. Habte/

Primary Examiner, Art Unit 1624

March 27, 2008